

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 10634-002001	Application No. 09/560,236
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Shutsung Liao et al.	
		Filing Date April 28, 2000	Group Art Unit 1616

U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
BB	AC	98/32444	07/30/1998	World Intellectual Property Organization	—	—		
	AD							
	AE							
	AF							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AG	Josef E. Herz, et al., "Fluorinated Sterols. Part II: 26,27 - Polyfluorinated Desmosterols", <u>Journal of Fluorine Chemistry</u> , Vol. 8, pp. 209-222 (1976)
	AH	Mohammed N. Iqbal, et al., "Bile Acids. LXXXI. Synthesis and structural assignment of E/Z isomers of substituted methyl hydroxy-5 β -cholest-24-en-26-oates", <u>Steroids</u> , Vol. 56, pp. 505-512 (October, 1991)
	AI	Naoyuki Koizumi, et al., "Synthesis of [25R] - and [25S]-25,26-Dihydroxyvitamin D31, <u>Tetrahedron Letters</u> , No. 32, pp. 2899-2902 (1978)
	AJ	A. Kuritzkes, et al., "3-epi-Uzarinin und 3-epi-17 α -Uzarinin", <u>Helvetica Chimica Acta</u> , Vol. 62, pp. 1502-1515 (1959)
	AK	Dieter Leibfritz, et al., "Nuclear Magnetic Resonance Spectroscopy. Carbon-13 Spectra of Cholic Acids and Hydrocarbons Included in Sodium Desoxycholate Solutions", <u>Journal of American Chemical Society</u> , Vol. 95, No. 14, pp. 4996-5003 (July 11, 1973)
BB	AL	S.H. Mujtaba Naqvi, "Chemical Synthesis and Mass Spectrometric Characterization of Some C-27 Steroids", <u>Steroids</u> , Vol. 22, pp. 285-290 (1973)
	AM *	J. Polonia, et al., "Die Konstitution des Xysmalogenins", <u>Helvetica Chimica Acta</u> , Vol. 42, pp. 1437-1447 (1959)
	AN *	C Tamm, et al., "Umwandlung von Cardenoliden durch Mikroorganismen. III. Umsetzung von Aglykonen und Glykosiden mit <u>Fusarium lini</u> ", <u>Helvetica Chimica Acta</u> , Vol. 42, pp. 239-259 (1959)
	AO *	R. Tschesche, et al., "Über pflanzliche Herzgifte. XIX. Mitteil. Die Glykoside der Uzara-Wurzel", <u>Chemische Berichte</u> , Vol. 85, pp. 1042-1053 (1952)
BB	AP	Stephen A. Ziller, Jr., et al., "Bile Acids. XXV. Allochenodeoxycholic Acid, A Metabolite of 5 α -Cholestan-3 β -OL in the Hyperthyroid Rat", <u>The Journal of Biological Chemistry</u> , Vol. 243, pp. 5280-5288 (1968)

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* English translation needed

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BB	AO	Summerfield et al., "Identification of Bile Acids in the Serum and Urine in Cholestasis", Biochem. J. 154:507-516, 1976.
	AP	Varma et al., "Synthesis and C-25 Chirality of 26-Hydroxycholesterols", The Journal of Organic Chemistry 40:3680-3686, 1975.
	AQ	Wei et al., "Modulation of Hormone-dependent Glucocorticoid Receptor Function Using a Tetracycline-regulated Expression System", J. Steroid Biochem. Molec. Biol. 64:1-12, 1998.
BB	AR	Xia et al., "Synthesis of N-Substituted 3-OXO-17 β -Carboxamide-4-AZA-5 α -Androstanes and the Tautomerism of 3-OXO-4-AZA-5-Androstenes", Heterocycles 47:703-716, 1998.

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
BB	AA	5,639,744	06/17/97	Marchi et al.	514	176	
BB	AB	5,466,815	11/14/95	Enhnen et al.	548	252	

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AC							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AD	Angelico et al., "Dissolution of Human Cholesterol Gallstones in Bile Salt/Lecithin Mixtures: Effect of Bile Salt Hydrophobicity and Various pHs", Scandinavian Journal of Gastroenterology 30:1178-1185, 1995.
	AE	Coleman et al., "Synthesis and Characterization of Novel Analogs of Conjugated Bile Acids Containing Reversed Amide Bonds", Journal of Lipid Research 36:901-910, 1995.
	AF	Janowski et al., "Structural Requirements of Ligands for the Oxysterol Liver X Receptors LXR α and LXR β ", Proc. Natl. Acad. Sci. 96:266-271, 1999.
	AG	Kim et al., "Inhibitors of Sterol Synthesis. Chemical Synthesis, Structure, and Biological Activities of (25R)-3 β ,26-dihydroxy-5 α -cholest-8(14)-en-15-one, a Metabolite of 3 β -hydroxy-5 α -cholest-8(14)-en-15-one", Journal of Lipid Research 30:247-261, 1989.
	AH	Kurosawa et al., "Synthesis of 3 α , 7 α , 12 α -trihydroxy-and 3 α , 7 α -dihydroxy-5 β -cholestan-26-oic Acids by the Use of β -ketosulfoxide", Steroids 60:439-444, 1995.
	AI	Li et al., "Sterol Synthesis. Preparation and Characterization of Fluorinated and Deuterated Analogs of Oxygenated Derivatives of Cholesterol", Chemistry and Physics of Lipids 99:33-71, 1999.
	AJ	Roda et al., "Synthesis and Physicochemical, Biological, and Pharmacological Properties of New Bile Acids Amidated with Cyclic Amino Acids", J. Med. Chem. 39:2270-2276, 1996.
	AK	Ruelle et al., "The Mobile Order Solubility Equation Applied to Polyfunctional Molecules: The Non-hydroxysteroids in Aqueous and Non Aqueous solvents", International Journal of Pharmaceutics 157:219-232, 1997.
	AL	Song et al., "Ubiquitous Receptor: A Receptor that Modulates Gene Activation by Retinoic Acid and Thyroid Hormone Receptors", Proc. Natl. Acad. Sci. 91:10809-10813, 1994.
	AM	Song et al., "Ubiquitous Receptor: Structures, Immunocytochemical Localization, and Modulation of Gene Activation by Receptors for Retinoic Acids and Thyroid Hormones", Annals of the New York Academy of Sciences 761:38-49, 1995.
BB	AN	Sweeny et al., "Metabolism of 5-fluorouracil to an N-cholyl-2-fluoro- β -alanine conjugate: Previously Unrecognized Role for Bile Acids in Drug Conjugation", Proc. Natl. Acad. Sci. 84:5439-5443, 1987.

Examiner Signature <i>B. Adis</i>	Date Considered <i>1/19/05</i>
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
BB	AA	2,698,853	1/1955	Wildi	260	397.2	
	AB	5,562,910	10/1996	Daynes et al.	424	278.1	
BB	AC	6,369,247	9/2002	Miller et al.	552	542	
	AD						
	AE						

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
BB	AF	123:286388	3/29/1995	China (Abstract Only)	—	—		
	AG							
	AH							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AI	Bleau et al. "Cholesterol sulfate. I. Occurrence and possible biological function as an amphipathic lipid in the membrane of the human erythrocyte." <u>Biochimica et Biophysica Acta</u> , Vol. 352(1), pp. 1-9, (1974)
	AJ	Dusza et al., "A Fusion Method for Preparation of Steroid Sulfates," <u>Steroids</u> p. 317-323 (1985).
	AK	Dusza et al., "The Preparation of Estradiol-17 β Sulfates with Triethylamine-Sulfur Trioxide," <u>Steroids</u> p. 303-315 (1985).
	AL	Charles Freudenreich, et al., "Design of Inhibitors from the Three-Dimensional Structure of Alcohol Dehydrogenase, Chemical Synthesis and Enzymatic Properties", <u>J. Am. Chem. Soc.</u> , pp. 3344-3353, (1984)
	AM	Bethany A. Janowski, et al., "Structural requirements of ligands for the oxysterol liver X receptors LXRA and LXRb", <u>Proc. Natl. Acad. Sci., USA</u> , Vol. 96, pp. 266-271, (January 1999)
	AN	Kornel et al., "Studies on Steroid Conjugates: II Chemical Synthesis and Characterization of Sodium Cortisol-21-Sulfate and Sodium Tetrahydrocortisol-3, 21-Disulfate," <u>Steroids</u> , p. 67-75 (1964).
	AO	Nambara et al., "Preparation of Specific Antiserum to Estriol 3-Sulfate 16-Glucuronide," <u>Journal of Steroid Biochemistry</u> , 21: p. 199-203 (1984).
BB	AP	Tanaka et al., "Specific Antisera for the Radioimmunoassay of Estradiol-3-Sulfate," <u>Journal of Steroid Biochemistry</u> , 22: p. 285-288 (1985).
	AQ	
	AR	

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
BB	AA	5,424,463	6/13/1995	Lardy et al.	552	637	
	AB	4,304,726	12/8/1981	Arakawa et al.	260	397.2	
	AC	4,193,930	3/18/1980	Chorvat	260	397.2	
BB	AD	4,125,544	11/14/1978	Dygos	260	397.4	
	AE						
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	AG						
	AH						
	AI						
	AJ						
	AK						

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	AL							
	AM							
	AN							
	AO							
	AP							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AQ	Database HPCAPLUS, AN 1974:461503, Bleau, G. et al. Cholesterol Sulfate, Occurrence and possible biological function as an amphipathic lipid in the membrane of the human erythrocyte. Biochim. Biophys. Acta, January 1974. Vol. 352, No. 1, pp. 1-9.
	AR	
	AS	
	AT	

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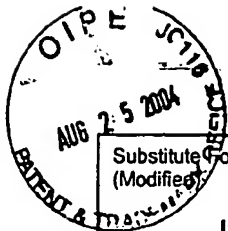
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
BB	AA	5,508,453	04/16/1996	Arosio et al.	552	553	
	AB						
	AC						

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AD							
	AE							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AF	Runong Wang et al., "Chemical Product Manual", the third version, Pharmaceuticals, Chemical Industry Publishing House, pp. 740 (January 1999)
	AG	
	AH	
	AI	

Examiner Signature <i>P. Arosio</i>	Date Considered <i>1/19/05</i>
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		Filing Date November 10, 2003	Group Art Unit 1614

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
BB	AA	2,698,853	1/04/1955	Wildi	—	—	
	AB	3,887,545	06/03/1975	Iacobelli et al.	—	—	
	AC	3,963,765	6/15/1976	Mazur et al.	—	—	
	AD	6,465,258 B1	10/15/2002	Shan et al.	—	—	
	AE	6,639,078 B1	10/28/2003	Haffner et al.	—	—	
	AF	6,645,955 B1	11/11/2003	Liao et al.	—	—	
	AG	US-2002-0107233-A1	08/08/2002	Liao et al.	—	—	
	AH	US-2002-0193357-A1	12/19/2002	Song et al.	—	—	
	AI	US-2003-0139385-A1	07/24/2003	Song et al.	—	—	
BB	AJ	US-2004-0014734-A1	01/22/2004	Song et al.	—	—	

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
BB	AK	EP 0 562 849 A2	09/29/1993	EPO	—	—		
	AL	WO 00/66611	11/09/2000	WIPO	—	—		
	AM	WO 02/062302	08/15/2002	WIPO	—	—		
	AN	WO 02/090375	11/14/2002	WIPO	—	—		
	AO	WO 03/039480	05/15/2003	WIPO	—	—		
BB	AP	WO 03/086303	10/23/2003	WIPO	—	—		

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
BB	AQ	Chawla et al., "Nuclear Receptors and Lipid Physiology: Opening the X-Files", <u>Science</u> , Vol. 294, pp. 1866-1870 (November 30, 2001).
	AR	Edwards et al., "BAREing it all: the adoption of LXR and FXR and their roles in lipid homeostasis", <u>J. Lipid Res.</u> , Vol. 43, pp. 2-12 (2002).
	AS	Hofmann, "The Continuing Importance of Bile Acids in Liver and Intestinal Disease", <u>Arch. Intern. Med.</u> , Vol. 159, pp. 2647-2658 (1999).
	AT	Kuritzkes, et al., "3-epi-Uzarigenin und 3-epi-17 α -Uzarigenin", <u>Helvetica Chimica Acta</u> , Vol. 62, pp. 1502-1515 (1959).
BB	AU	Laffitte et al., "LXRs control lipid-inducible expression of the apolipoprotein E gene in macrophages and adipocytes", <u>PNAS</u> , Vol. 98, pp. 507-512, (June 16, 2001).

Examiner Signature

P. Radis

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Other Documents (include Author, Title, Date, and Place of Publication)		
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BB	AV	Lange et al., "Cholesterol Movement in Niemann-Pick Type C Cells and in Cells Treated with Amphiphiles", <u>The Journal of Biological Chemistry</u> , Vol. 275, No. 23, pp. 17468-17475, (June 9, 2000).
	AW	Makishima et al., "Identification of a Nuclear Receptor for Bile Acids", <u>Science</u> , Vol. 284, pp. 362-365 (1999).
	AX	Roda et al., "Advances in Bile Acid Therapy", <u>Dig. Dis. Sci.</u> , Vol. 34, pp. 24S-35S (1987).
	AY	Roda et al., "New 6-substituted bile acids: physico-chemical and biological properties of 6 α -methyl ursodeoxycholic acid and 6 α -methyl-7-epicholic acid", <u>J. Lipid Res.</u> , Vol. 35, pp. 2268-2279 (1994).
	AZ	Song et al., "Auto-oxidized cholesterol sulfates are antagonistic ligands of liver X receptors: implications for the development and treatment of atherosclerosis", <u>Steroids</u> , Vol. 66, pp. 473-479 (2001).
	AAA	Song et al., "Cholesteniic Acid Is a naturally Occurring Ligand for Liver X Receptor α ," <u>Endocrinology</u> , Vol. 141 pp. 4180-4184 (2000).
	ABB	Song et al., "Hypolipidemic effects of selective liver X receptor alpha agonists", <u>Steroids</u> , Vol. 66, pp. 673-681 (2001).
	ACC	Song et al., "Selective Activation of Liver X Receptor Alpha by 6 α -Hydroxy Bile Acids and Analogs," <u>Steroids</u> , Vol. 65 pp. 423-427 (2000).
	ADD	Susan Budavari, EDITOR, <u>The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals</u> , 11 th Edition, published by Merck & Co., Inc., pp. 396, 574, 1225-1226 (1989).
	AEE	Whitehouse et al., "Catabolism in vitro of cholesterol: some comparative aspects", <u>Arch. Biochem. Biophys.</u> , Vol. 98, pp. 305-311 (1962). (Abstract Only)
BB	AFF	Xuan Fu et al., "27-Hydroxycholesterol Is an Endogenous Ligand for Liver X Receptor in Cholesterol-loaded Cells", <u>The Journal of Biological Chemistry</u> , Vol. 276, No. 42, pp. 38378-38387 (2001).

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U.S. Patent Documents

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BB	AA	3,784,598	01/08/74	Iseli et al.	—	—	
	AB	3,925,480	12/09/75	Thal et al.	—	—	
	AC	4,006,172	02/01/77	Salmond	—	—	
	AD	4,125,544	11/14/78	Dygos	—	—	
BB	AE	4,639,420	01/27/87	Schaffner	—	—	

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							Yes	No
BB	AF	GB 1 405 818	09/10/75	Great Britain	—	—		
BB	AG	GB 2 009 180	06/13/79	Great Britain	—	—		

Other Documents (include Author, Title, Date, and Place of Publication)

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BB	AH	Bergmann et al., "Contribution to the study of marine products. XXXI. Palysterol and other lipid components of sea anemones", <u>Journal of Organic Chemistry</u> , 16:1337-1344 (1951).
	AI	Boto et al., "Tandem b-Fragmentation-hydrogen Abstraction Reaction of Alkoxy Radicals in Steroid Systems", <u>Journal of Organic Chemistry</u> , 62(9):2975-2981 (1997).
	AJ	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 1274114, XP002284519.
	AK	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , Citation No. 575886, BRN 45135, 41670, XP002284520.
	AL	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 1629436, XP002284521.
	AM	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 1355280, XP002284522.
	AN	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 41863, XP002284523.
	AO	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 39425, XP002284524.
	AP	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 1272804, XP002284525.
	AQ	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 4723631, XP002284526.
	AR	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 6282221, XP002284527.
BB	AS	Database Beilstein 'Online!', <u>Beilstein Institute for Organic Chemistry</u> , BRN 6781196, XP002284528.

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BB	AT	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 7545061, XP002284529.
	AU	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 7950623, XP002284530.
	AV	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 7954188, XP002284531.
	AW	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 2017533, XP002284532.
	AX	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 2024248, XP002284533.
	AY	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 2033596, XP002284534.
	AZ	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 2064766, XP002284535.
	AAA	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 2065735, XP002284536.
	ABB	Database Beilstein 'Online!', Beilstein Institute for Organic Chemistry, BRN 8881860, XP002284537.
	ACC	Djerassi et al., "Mass Spectrometry in Structural and Stereochemical Problems. LXV. Synthesis and Fragmentation Behaviour of 15-Keto steroids", <u>Journal of the American Chemical Society</u> , 87(4):817-826 (1965).
	ADD	Gao et al., "A Novel Method for the Synthesis of a C/D-Ring Synthon of Vitamin D Derivatives From Hyodeoxycholic Acid", <u>Tetrahedron Letters</u> , 40(1):131-132 (1999).
	AEE	Kasal, "Epalons: 6-Substituted Derivatives of 7-Norepiallopregnanolone", <u>Tetrahedron</u> , 56(22):3559-3565 (2000).
	AFF	Lardy et al., "Ergosteroids II: Biologically Active Metabolites and Synthetic Derivatives of Dehydroepiandrosterone", <u>Steroids: Structure, Function and Regulation</u> , 63(3):158-165 (1998).
	AGG	Liebermann et al., "D5-Cholestene-3b, 4b, 7a-triol and the Inhibition of the Oxidation of Hydroxyl Groups by Vicinal Substituents", <u>Journal of the American Chemical Society</u> , 72:5211-5218 (1950).
	AHH	McMorris et al., "Structures of Ogoniol-1, -2, and -3, Steroidal Sex Hormones of the Water Mold", <u>Journal of the American Chemical Society</u> , 97(9):2544-2545 (1975).
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	ALL	Teng et al., "Sterol Metabolism. XX. Cholesterol 7b-Hydroperoxide", <u>Journal of Organic Chemistry</u> , 38:119-123 (1973).
BB	AMM	Witiak et al., "Inhibitors and Stimulators of Cholesterolgenesis Enzymes", <u>Journal of Medicinal Chemistry</u> , 14(8):684-693 (1971).

Examiner Signature <i>Padio</i>	Date Considered <i>11/19/05</i>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified) NOV 22 2004 Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 10634-002002	Application No. 10/705,398
	Applicant Shutsung Liao et al.		
	Filing Date November 10, 2003	Group Art Unit 1614	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
BB	AA	Clinton et al., "D-Homosteroids. I. Derivatives of D-Homoetiocolan-3 α -ol-11,17 α -dione", <u>Journal of the American Chemical Society</u> , 79:6475-6480 (1957).
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	AC	DeMarcano et al., "D-Homoandrostanes.2.Preparation and Properties of some Dioxygenated D-Homo-5 α -Androstanes", <u>Journal of Organic Chemistry</u> , 42(7):1221-1225 (1977).
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